

COMPLAINANT v SYRIMED (THAME LABORATORIES)

Representatives examination

CASE SUMMARY

This case was in relation to an allegation that a named employee had been promoting medicines to health professionals for more than two years without the requisite representative qualification.

The outcome under the 2021 Code was:

No Breach of Clause 5.1	Requirement to maintain high standards at all times
No Breach of Clause 9.4	Requirement that representatives take an appropriate examination within their first year of employment as a representative and pass it within two years of starting such employment

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A complaint was received from a contactable ex-employee of SyriMed (formerly Thame Laboratories) about the company.

COMPLAINT

The complaint wording is reproduced below:

‘[The] company have been asking an employee to market branded pharmaceutical drugs to clinicians without an ABPI qualification. The employee is called [named employee]. [They have] not done the ABPI course but [they have] been marketing and promoting drugs to both GP[s], Phamrcists [sic] and hospital clinicians. [They have] been selling Alfredo’s [sic], Miprosed, and Zacco to doctors. I told the pharma company [named employee] must have a ABPI [sic] in order to sell these drugs but hey [sic] did not take my advice. [Named employee] has been promoting these for over 2 years now. ‘

When writing to SyriMed, the Authority asked it to consider the requirements of Clauses 5.1 and 9.4 of the Code.

SYRIMED'S RESPONSE

The response from SyriMed is reproduced below:

“We, Syri Ltd, value and respect the PMCPA code as a cornerstone for maintaining a safe and ethical healthcare environment for patients and healthcare professionals. Following receipt of the complaint, we have thoroughly investigated the matter and are committed to upholding the highest standards and continuing respect of the PMCPA code.

Upon receiving your correspondence on April 11th 2023, we carefully reviewed the complaint concerning our employee, [named employee].

Please note, the complaint listed a brand called Alfredo's. We believe this refers to a brand we have a marketing authorisation for, registered as 'Alfreded.'

In addition, on 11th April 2023 we received further correspondence to confirm the complainant was an Ex-employee.

Finally, on 16th May 2023 we received additional correspondence to confirm that despite the complainant indicating they would send additional information in support of their complaint, nothing transpired. Hence, there was no addition information to consider before our response.

Therefore, considering all the information received, please see below our response with all relative information regarding the submitted complaint as of this date, 30th May 2023.

1. Role Performed by Employee

[Named employee] joined our organization in [month] 2012, working for B&S Distribution, a sister company to Syri Ltd. [Their] role at that time was [job title] within B&S Distribution, which primarily dealt with wholesale and retail pharmacy customers. The responsibilities of [their] role included various administrative tasks related to customer orders, inquiries, deliveries, and price management, see responsibilities below:

- Taking phone orders (from retail pharmacies)
- Screening and releasing web orders.
- Screening and releasing Purchase Orders.
- Reviewing product, price, and order queries.
- Sending Order forms, invoices, credit invoices, COC's etc.
- Chasing and Solving delivery queries.
- Quoting prices for unlicensed (specials) manufacturing products
- Negotiating prices on bulk orders.
- Checking stock availability in system.

It is important to note that during this period, [named employee]'s interactions were solely limited to Retail & Wholesale customers. Product specific queries that would be dealt with by [named employee] were Restricted to a commercial nature.

In the time since 2012, Syri Limited became a larger business with a growing portfolio of licenced [sic] medicines. In that time [named employee]'s role remained consistent, but [they] gradually shifted focus to wholesale accounts only. Syri limited did not hold any product licences at the time.

In 2020 as our portfolio diversified and included branded products, we employed an experienced [sales employee] and [market access employee]. [Named employee]'s role and title were subsequently changed to [job title that included the word 'sales']. [Named employee]'s role was primarily administrative support for the newly appointed [sales and market access employees].

The changes to [named employee]'s roles and responsibilities are as below:

Additional duties;

- Data analysis and reporting- reviewing sales data and preparing PowerPoint slides for internal use.
- arranging for printing of marketing materials once these have been approved by the final signatory.

In November 2022, Syri Ltd underwent a sales department restructuring, rendering [named employee]'s current role obsolete. As a long-standing employee, we felt obligated to support [their] career development within our organization. Consequently, on November 4, 2022, we communicated to [named employee] that [their] role needed to evolve, and we enlisted the assistance of our fully ABPI-qualified [market access employee] to closely guide and train [them] for a potential role [in market access]. This decision was made in compliance with Clause 5.1 of the 2021 code, which emphasizes the maintenance of high standards at all times.

To date, [named employee]'s communication has been limited, supervised, and restricted to previously approved commercial information upon request. [They have] not conducted any clinical or public-facing presentations regarding our licensed products to healthcare professionals. However, as part of [their] training and development [they have] shadowed such scenarios. [Their] communication has been strictly related to commercial aspects such as pricing, savings, and product availability.

To this date (30th May 2023), [named employee] has not been given a clinical or public facing role. We assure you that [named employee] will continue to receive close supervision, training and development until [they demonstrate] competence to take on such a role or until [they decide] to pursue other roles in our business or otherwise.

2. Examination Status

In accordance with Clause 9.4 of the 2021 code (16.3), representatives are required to take an appropriate examination within their first year of employment and pass it within two years. The examination should be accredited to at least Level 3 or its equivalent by an external awarding body recognized by Ofqual.

Considering these guidelines, we have taken note of the date, November 4, 2022. If [named employee] becomes involved in any activities that could potentially influence

healthcare professionals in a market access role, [they] will be required to register for the Compulsory ABPI Intermediate professional program no later than November 4, 2023. Additionally, [they] will need to successfully complete the ABPI qualifications by November 4, 2024. This ensures compliance with the code's requirements.

3. Summary

In response to the complaint, we firmly believe that we have adhered to Clause 5.1 of the 2021 code in all aspects. We have actively addressed the situation by discussing and exploring potential roles for [named employee], implementing a mentorship program with on-the-job training, and establishing an education structure to facilitate [their] personal development and potential promotion within our organization.

We have duly taken note of the dates when we discussed the potential change in [named employee]'s role, ensuring that if [they demonstrate] competence and expresses a desire to pursue a market access role, [they] will be registered in the mandatory ABPI programs as required by Clause 9.4 of the 2021 code.

We appreciate your attention to this matter and assure you of our unwavering commitment to maintaining the highest standards of professionalism and compliance with the ABPI code of conduct.”

PANEL RULING

The Panel noted the complainant's allegation that for more than two years a named employee had been promoting Alfresed, Miprozed and Zacco to general practitioners, pharmacists and hospital clinicians, without the requisite representative qualification. The Panel noted that the complainant provided no evidence in support of their allegation.

The PMCPA was not an investigatory body. All complaints were judged on the evidence provided by the parties. The Authority asks the respondent company for a complete response. The complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted the definition of a Representative in Clause 1.19 of the Code as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines.

The Panel further noted the broad definition of promotion in Clause 1.17 as any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

Clause 9.4 of the Code stated, among other things, that representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment. An appropriate examination can be either the relevant ABPI examination (for medical or generic sales representatives) or an examination of at least the same standard which covers similar content and learning material as the corresponding ABPI examination. The supplementary information to Clause 9.4 (Time allowed to pass an examination) stated, among other things, that prior to passing an appropriate examination, representatives may be engaged in such employment for no more than two years,

whether continuous or otherwise and irrespective of whether with one company or with more than one company.

The Panel had no information about the employee in question's previous employment history prior to joining SyriMed.

The Panel noted SyriMed's submission that the employee in question joined the company in 2012 and that the responsibilities of their role were administrative and were described as:

- Taking phone orders (from retail pharmacies).
- Screening and releasing web orders.
- Screening and releasing Purchase Orders.
- Reviewing product, price, and order queries.
- Sending Order forms, invoices, credit invoices, COCs etc.
- Chasing and Solving delivery queries.
- Quoting prices for unlicensed (specials) manufacturing products.
- Negotiating prices on bulk orders.
- Checking stock availability in system.

The Panel noted SyriMed's submission that in 2020, as a result of changes within the company, the employee in question's role and job title changed to [job title which included the word 'sales']. The Panel noted SyriMed's submission that this role was primarily administrative support for the newly appointed [sales and market access employees]. SyriMed submitted that the employee in question's responsibilities, in addition to the those cited above, were:

- Data analysis and reporting - reviewing sales data and preparing PowerPoint slides for internal use.
- Arranging for printing of marketing materials once these had been approved by the final signatory.

The Panel queried whether the job title [which included the word 'sales'] implied that the individual was a 'Representative' as defined in the Code. However, noting the roles and responsibilities described above, on the evidence before it, the Panel considered that the complainant had not established, on the balance of probabilities, that the employee in question was calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines while carrying out the above roles and responsibilities from 2012 until 4 November 2022.

The Panel noted SyriMed's submission that in November 2022 it underwent a sales department restructuring which required the employee in question's role to evolve and on 4 November 2022 they began training for a potential role [in market access]. SyriMed submitted that to date (30 May 2023), the employee in question's communication had been limited, supervised and restricted to previously approved commercial information upon request. According to SyriMed, the employee in question had not conducted any clinical presentations regarding the company's licensed products to health professionals, however, they had shadowed such scenarios; their communication had been strictly related to commercial aspects such as pricing, savings and product availability.

Noting the broad definition of promotion, the Panel considered that the employee in question was, on the balance of probabilities, acting as a Representative as defined by the Code from 4 November 2022. In reaching this decision, the Panel particularly bore in mind that, from 4 November 2022, the employee was required to attend meetings with health professionals about SyriMed's medicines and to communicate product information such as savings.

Bearing in mind the requirements of Clause 9.4 as stated above, the Panel considered that the employee in question had until 3 November 2023 to take the appropriate representatives examination and until 3 November 2024 to pass it.

The Panel was concerned by SyriMed's submission that if the employee in question became involved in any activities that could potentially influence healthcare professionals in a market access role then they would 'register' for the examination no later than 4 November 2023. The Panel considered that the employee in question was a representative as defined by the Code from 4 November 2022. The Panel noted that Clause 9.4 required representatives to 'take an appropriate examination within their first year of employment as a representative' which, in the Panel's view, meant they must attempt all modules that make up the appropriate examination and not just 'register' for it.

Nonetheless, the Panel considered the complainant had not established that the employee in question had been a representative, as defined by the Code, for a year at the time the complaint was made. The Panel considered that at the time the complaint was made in April 2023, and responded to by SyriMed in May 2023, the employee in question still had time (until 3 November 2023) in which to take the examination, and therefore the Panel ruled **no breach of Clause 9.4**.

Noting its ruling of no breach of Clause 9.4 of the Code and the narrow allegation, the Panel considered that the complainant had not established that SyriMed had failed to maintain high standards in this regard and the Panel consequently ruled **no breach of Clause 5.1**.

Complaint received **10 April 2023**

Case completed **7 June 2024**